An Observational Study on Type 2 Diabetes Mellitus related risk factors and complications in in-patient department at a tertiary care centre in Telangana, India.

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ABSTRACT

Aims: To identify the risk factors and complications of type 2 diabetes mellitus (T2DM).

Study design: It is a single-centre, prospective, observational study.

Place and Duration of Study:This study site includes in-patient departments of Gandhi Hospital, Secunderabaddone for a period of six monthsbetween December'2022 to May'2023.

Methodology: In-patient cases diagnosed with T1DM, T2DM and pre-diabetes were included in study. A data collection form was drafted that included patient demographics (age, sex, height, weight, history in family, risk factors, past medication history, past medical illnesses- HTN (hypertension), dyslipidemia. Lifestyle of patients if physically active/ sedentary and social history as smoker/ alcoholic noted. Fasting Blood Sugar (FBS) was recorded for T2DM along with BMI in kg/m^2.Any micro or macro-vascular complications noted during study period. Medications prescribed were assessed for appropriateness in treating Diabetes Mellitus.Case sheets with complete information regarding patient details were only analyzed.

Results:70 cases were collected and analyzed for diabetes out of which 58 cases comprised of T2DM. The majority study population was males 63.79% and with age group 53-69 years (25 cases, 43.10%) being higher. As per WHO-Diabetes Criteria, Pre-Diabetes was highly prevalent of 58.57% at this study site. Higher cases of T2DM (82.85%) was noted which shows the importance of implementing lifestyle changes to prevent macro and micro vascular complications. Symptoms ofT2DM were abdominal pain (15, 25.86%) followed by excessive thirst (20.68%), and tiredness (10%). Major risk factors for T2DM were hypertension (15, 25.86%), smoking habit (22.41%), alcohol and obesity (17.24% each) which may have lead to complicationsassociated with T2DM as Nephropathy in 2 cases followed by retinopathy, ischemic stroke, and diabetic foot each1 case.Metformin as monotherapy (82.75% cases) was preferred treatment for T2DM at this site followed by Glimepiride (12, 20.68%).

Conclusion: Study observations conclude that various risk factors can lead to T2DM, hence it is essential to create awareness among the general population on this. Strategies for preventing DM should also be highlighted such as lifestyle changes and following

proper dietary guidelines that would avertany life-threateningconditions.

Keywords: Type 2 Diabetes Mellitus, risk factors, complications, patients

1. INTRODUCTION

Diabetes remains one of the four most prevalent non-communicable diseases (NCDs) in the world. It results in disability and premature death while creating an increasing burden on health systems, economic development, and the well-being of a large proportion of the global population. The most common forms of diabetes are type 1 diabetes, in which complete insulin deficiency causes the destruction of the pancreatic beta cells, and type 2 diabetes, in which insulin resistance can lead to hyperglycemia. Most diabetes cases (up to 95% of diabetic patients) are type 2 diabetes (so-called insulin-independent).

The International Diabetes Federation (IDF) estimates that as of 2021 there were 537 million people with diabetes worldwide, and this was predicted to increase to 783 million by 2045. The incidence of diabetes is more prevalent in highly developed countries, but the highest rate of increase in cases is in developing countries. The continuing upward trend is mainly caused by the increase in the number of diabetes patients with type 2 diabetes, which is attributed to population growth and aging (39.7%), increased incidence (28.5%), and the interaction of these two factors (31.8%). It is widely believed that the main cause of type 2 diabetes is a high-energy Western-style diet combined with a sedentary lifestyle, which underlines the role of lifestyle as the most important risk factor for type 2 diabetes.The level of patients' knowledge of diabetes plays an important role in the self-management of the disease. It is considered that patients with good disease knowledge have a better understanding of the nature and consequences of diabetes and are less prone to various complications and severe exacerbations of diabetes [1].

Type 2 diabetes mellitus (T2DM) is one of the most common metabolic disorders majorly affecting the adult population. It accounts for 90–95% of all diabetes cases. Long-term elevations in blood glucose levels contribute to many complications in various organs, including the kidneys, skin, nerves, heart, and blood vessels.[13] This rise in blood glucose, particularly after diagnosis, is mainly due to a lack of compliance with the management plan that involves lifestyle modification and pharmaceutical interventions.One of the main impairment occurring from hyperglycemia is damage to the vasculature. It occurs either at small (microvascular complications) or large blood vessels (macro-vascular complications). Diabetic retinopathy is the most common microvascular complication, followed by diabetic nephropathy and neuropathy. All macro-vascular complications arise from the development of atherosclerosis, which gradually causes the narrowing of arterial walls.

It is also necessary recognizing the management strategies practiced as treatment and prevention to prevent immediate and long-term complications, and enhance the patient's quality of life. Hence, the study was aimed to assess T2DM complications, their management practice, and risk factors attributed to the existence of complications [2].

2. MATERIAL AND METHODS

2.1 Aim: To know the prevalence of Type 2 Diabetes Mellitus at the study site.

2.2 Objectives: To assess the risk factors, complications connected with Type 2 Diabetes Mellitus. To observe themanagement practices in treatment of Type 2 DM patients.

2.3Study Design: It is a single center Prospective Observational Study done in the In-patient Departments of Gandhi Hospital, Secunderabad during the study period from December'2022 to May'2023, for six months duration. A total of 70 cases were collected of T1DM and T2DM which included Pre-Diabetes also.

2.4Inclusion Criteria

As per WHO DM Guidelines the criteria for Pre-diabetes was a FBS (fasting blood sugar) of (100-125) mg/dl and ≥ 126 mg/dl as Diabetes. A value <100mg/dl was considered as healthy individual. The study population of ages equal to and more than two years, diagnosed with either Pre-diabetes or T2DM were included in the study. Data was collected from In-patients of General Medicine Department, Gastroenterology Department and Paediatrics Department.

2.5Exclusion Criteria

Cases having normal levels of FBS excluded.Lactating and pregnant women, terminally ill patients and out-patients departmentwere not included in study. Cases with incomplete data and without proper discharge summary not considered.

2.6 Study Procedure

The study data was gathered by utilizing a data collection form that included patient demographics (age, sex, height, weight, history in family, risk factors, past medication history, past medical illnesses- HTN (hypertension), dyslipidemia. Lifestyle of patients if physically active/ sedentary amd social history as smoker/alcoholic was noted. On physical examination Blood pressure was recorded using a sphygmomanometer and presence of HTN was diagnosed based on JNC 7 criteria (Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure). BMI was recorded and the standard cut- off for Asians being overweight was if more than 23 kg/m^2. The blood glucose levels were measured by the FBS test when patient fasted for 10 hours prior to withdrawal of blood samples. Patients who stopped smoking and alcohol <1 year ago were also included in this study along with current smokers and alcoholics. All cases followed up until discharge to check for any complications developed in study period.

Sample Size Selection: A total of 70 cases were collected having and evaluated for Pre-Diabetes and DM as per the WHO-DM Criteria. Furthermore, the 70 cases were categorized into T1DM and T2DM by the end of the study period which showed T2DM to be of 58 cases in total. As the T2DM cases were observed higher in number the study was designed specific to T2DM parameters.

The medications prescribed were assessed for appropriateness in treating Diabetes Mellitus.Case sheets with complete information regarding patient details were included.

2.7 Data Analysis

All the gathered data was entered in excel sheet and analyzed for study report. Means and standard deviations were used for normally distributed numerical variables. Descriptive data analyzed and presented as percentages.

3. RESULTS AND DISCUSSION

Cases were collected from In-patients Department of Gandhi Hospital at a tertiary care centre. A total of 70 cases were collected and evaluated as per WHO criteria for DM where Pre-diabetes Mellitusseen in 41 (58.57%) cases and 29 (41.42%) cases with DM (>= 126mg/dl). By the end of the study period out of 70 cases T1DM were 12 (17.15%) and T2DM were 58 (82.85%) was observed. The higher numbers of T2DM cases was due to the progression of Pre-diabetes patients to T2DM in due to course of time and thereby making this study to highlight majorly on T2DM related aspects. This was analogous to a study done by **KubaSekowski et al.,** which also showed maximum cases of T2DM (56.4%) and T1DM of (15.5%) and (11.8%) of GDM, at their study site of Warsaw, Poland [1].

Hence this study included 58 T2DM that wereanalyzed and interpretedas follows. Majority of patients comprised of males 37 patients (63.79%) followed by females 21 patients (36.20%).The vast majority of patients were having ages between 53-69 years (25, 43.10%), followed by 12 patients (20.68%) of age group 36 -52 , and again followed by 12patients (20.68%) of age group > 70 years, followed by 5 patients (8.62%) of age group 2-18,and only 4 patients (6.89%) of age 19-35.This was similar to a study done by **JagadeeshaAravinda** which showed average age of patients having DM to be 53.28 years [3]. Most cases were collected from general medicine ward 51 cases (87.93%), from Gastroenterology 5 cases were collected (8.62%), and then from pediatric 2 cases were collected (3.44%).

This study shows high prevalence of Pre-diabetes in this population who are prone to develop DM, eventually, if no appropriate lifestyle modifications are followed. This data can be co-related to a study done by **Wu S et al.,** on pre-diabetics of mexican-americans who were assessed for 27 months and out of which one-third of them transitioned to DM, which was mainly due to increased BMI (basal metabolic rate) and worsening metabolic health[4]. This was similar to our study that reported all 58 cases having BMI over 23 kg/m^2 . A study by **MuthunarayananLogaraj et al.,** demonstrated similar BMI > 23 in Pre-Diabetes and DM patients [5].

Hence, it is imperative to monitor Pre-diabetes population for old age, waist circumference, poor diets, hypertension, hypercholesterolemia and obesity which are factors for Pre-diabtetes progression to T2DM, which can also lead to micro and macro-vascular complications as noted in a study by **Rahim FF** [6]. Furthermore, diet rich in

carbohydrates, sedentary lifestyle have contributed to T2DM transition faster from Pre-diabetes. The interventions for Pre-diabetes patients include screening the plasma glucose levels, implementing lifestyle changes by increased physical activity that can hinder one form developing T2DM and leading to better quality of life or may delay the progression to T2DM. In a study by **Beulens J et al.,** it has been demonstrated that ethnicity being a major risk factor for progression to T2DM from Pre-DM was more in Asian adults making India a major region of having massive T2DM cases in near future [7].

In majority of the cases the symptom was of abdominal pain 15 (25.68%) and then followed by 12(20.68%) cases were seen as thirsty and then 10 (17.24%) cases were seen as tiredness and 3 (5.17%) were seen as slow healing of cuts and wounds and then followed by 5 (8.62%) cases were seen as symptoms as frequent urine output, headache, were seen as 4 (6.89%) and 3 (5.17%) nausea/vomitings were seen and dizziness were seen as 2(3.44%) and then 3(5.17%) cases were seen as sudden weight loss.Another study done by **KubaSekowski et al,** demonstrated polyuria (42%) followed by thirst increase (57%) as major symptoms of T2DM [1].

Table 1 shows the risk factors for type 2 DM as the majority of instances were seen as risk factor as smoking habit 13(22.41%) cases and then followed by 15(25.86%) cases were seen as risk factor hypertension and then followed by 10(17.24%) cases were seen as risk factor obesity and then followed by 10(17.24%) cases were seen as risk factor as alcohol consumption and then 5(8.62%) cases were seen as risk factor of age >45 yrs are at high risk and then 2(3.44%) cases were seen as risk factor of sedentary lifestyle and then 3(5.17%) cases were seen as risk factor of pre diabetic. This showed similarity with another study done by **DebrahAsiimwe et al**, that showed HTN, smoking, alcohol, obesity to be common risk factors [8].

Table 1: Risk Factors For Type 2 DM

Risk factors	Number of cases	Percentage%
Hypertension	15	25.86%
Smoking habit	13	22.41%
Alcohol consumption	10	17.24%
Obesity	10	17.24%
Sedentary lifestyle	2	3.44%
Age > 45 yrs high risk	5	8.62%
Pre-diabetic	3	5.17%
Total	**58**	**100%**

The common complication for T2DM was Nephropathy in 2 cases, followed by Retinopathy, Ischemic stroke and diabetic foot each having one case. However at our study site the complications associated with T2DM were fairly less observed in patients. In a study done by **ZenebeNegash**it was seen that maximum complications with T2DM was with Neuropathy(36.3%), Nephropathy(8.1%), Retinopathy(6.6%), which wasn't the case with our study findings [2].

As per the study by **Khan RMM et al.,** the risk factors of our study that could have been possible reasons for occurrence of T2DM and complications are as follows [9]:

- **Hypertension**: It has been observed that DM and HTN are due to metabolic complications mainly due to obesity and increased cholesterol. However, T2DM patients have HTN, are obese due to sedentary life styles which promotes increased levels of cholesterol making them prone to developing stroke conditions as seen in our study. Therefore, maintaining a physically active lifestyle helps in taking up of plasma glucose by active smooth muscles contractions and this improves insulin sensitivity by 15%.
- **Smoking** leads to T2DM as the nicotine causes destruction of Beta cells due to over exposure of nicotine along with reduction in insulin sensitivity. This combined with excess alcohol intake worsens the T2DM.
- **Age** of > 45 years are prone to T2DM as aging causes the body to become less sensitive to insulin causing Beta cells of pancreas to alter and show insufficiency to insulin production.

Pre-diabetes can lead to T2DM if left undiagnosed or treated late and leading to complications as mentioned above in our study such as:

- **Retinopathy** in T2DM as a complication is mainly due to increased corneal blood pressure in the eye due to presence of HTN and activation of renin-angiotensin-aldosterone system in the patient.
- **Nephropathy** most commonly seen in T2DM than in T1DM as a complication due to delayed diagnosis of T2DM. The contributing factor is HTN as in our study and slowly decreases the glomerular filteration rate in the patient over time.
- **Diabetic Foot** is a peripheral nerve dysfunction as seen in a case in our study. It occurs due to uncontrolled T2DM where patient has been undiagnosed for long periods of time which could have otherwise been prevented with glycemic control and timely medication treatment.

The medications for T2DM were taking single drugs (monotherapy) 48(82.75%) cases were seen as taking metformin and then followed by 10 (17.24%) cases were seen as taking glimepiride from total 58 cases.Another study done by **ZenebeNegash et al,** demonstrated maximum usage of combination therapy of metformin and glimepiride followed by only metformin as mono-therapy [2]. **Table 2**shows that the length of hospital stay of type 2 DM that is seen as no cases were found on 1st and 2nd day wise and 10 (17%) cases were seen on 3rd day and then 12 (20%) cases were seen on 4th day and

then 36 (62%) cases were seen on 5th day final day from total 58 cases.This shows that 5 days time period is required for a patient hospitalized for T2DM to stabilize before getting discharged.

Table 2: Length of Hospital Stay of Type 2 DM

Day Wise	Number of Cases	Percentage%
Day One	0	0%
Day Two	0	0%
Day Three	10	17%
Day Four	12	20%
Day Five	36	62%
Total	58	100%

3.1 Prevention Points for avoiding T2DM associated complications:

Make a commitment to managing your diabetes.

Don't smoke and avoid tobacco chewing.

Keep your blood pressure and cholesterol level under control by limiting intake of salt and fatty foods.

Schedule regular physicals and eye exams to prevent any life threatening complications associated with diabetes.

Keep your vaccines up to date.

Take care of your teeth.

Pay attention to your feet as it may lead to diabetic foot as a complication.

Maintain a normal body weight to regulate metabolism and insulin regulation.

Limit alcohol consumption.

Manage your stress conditions by participating in meditation or yoga.

Choose drinks without added sugars, preferring natural fruit juices.

Eat plenty of fruits and well cooked vegetables.

Take a balanced carbohydrate-controlled diet.

4. CONCLUSION

The study has showed important findings of complications of T2DM, risk factors and possible medical management.However, it is inappropriate to generalize the findings of this study to general population diagnosed with T2DM. This is due to limited duration of our study, low sample size and single center. Hence, expanding the study population to a larger size in various other study sites can help understand the risk of DM better.For better understanding of this disease it requires improvement and advancement of education

programs to create awareness in the public.People should also be given awareness on life style changes such as exercising, eating fruits and vegetables to maintain a normal BMI (Body mass index) and have a good healthy life, preventing DM. However, This study has not showed severity of complications and its outcome and management. Thus, the risk DM causes on one's health or causing medical conditions not quoted in detail.

5. **Study Limitations:** This research has not studied factors causing pre-diabetes so by understanding these factors it will help in early interventions on lifestyle changes to prevent T2DM. As the duration of study was limited only few complications were observed. Hence, by extending the study period might unable to observe other macro or microvascular complications. Only FBS values were used to determine the T2DM at this site. But, introducing of other blood glucose tests as OGTT (oral glucose tolerance test), HbA1c might help in accurate T2DM diagnosis. Use of ADA (American Diabetes Association) criteria for appropriate diagnosis of pre-diabetes and DM can be helpful.

6. **Areas of future research:** Use of other classes of anti-diabetic drugs can be taken intro consideration such as SGLT2 (sodium glucose transport protein 2) inhibitors and GLP-1 (Glucagon-like peptide-1) receptor agonist [10, 14]. Prediction of who progress from pre-diabetes to T2DM requires more detailed research. An extensive research on how pre-diabetes can lead to micro andmacrovascular complications can be undertaken so that medical interventions can be implemented timely for better clinical outcomes. Also cost-effective strategies can be developed as all patients may not be economically stable.

CONSENT

All authors declare that 'written informed consent was obtained from the patient (or other approved parties) for publication of this research work. A copy of the written consent is available for review by the Editorial office/Chief Editor/Editorial Board members of this journal."

ETHICAL APPROVAL

All authors hereby declare that the study was examined and approved by the Institutional ethics committee CMR College of Pharmacy, (CMRCP/IEC/2022-23/11).

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